



IRIS Assessment Plan for Oral Exposure to Ammonia and Ammonium Salts

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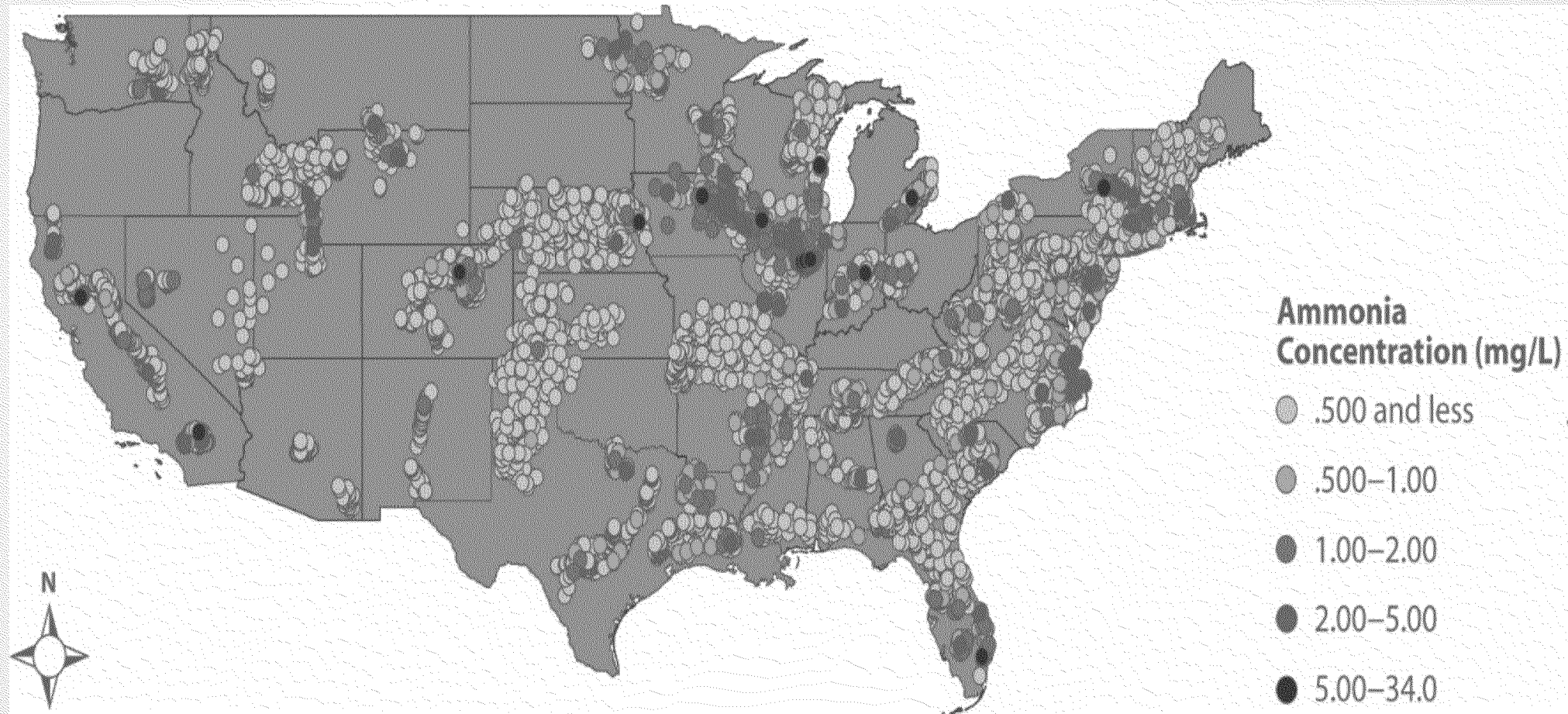


EPA's Interest in Ammonia

- Ammonia is a high-volume contaminant due to its use in fertilizers and its presence in runoff water from agricultural fields
 - U.S. production is tens of billions of lbs/yr
- Ammonia is certified for use in water and wastewater treatment
 - Most notably in the disinfection of drinking-water by chloramination
- Ammonia and 23 ammonium compounds are listed as hazardous substances under CERCLA section 102(a)
- Health authorities need an oral reference dose to evaluate protection of public health in high-contamination situations



Ammonia in U.S. Groundwater



Prepared by OW, based on USGS National Water-Quality Assessment Program data from 2011



History

- IRIS, 1991: inhalation reference concentration of 0.1 mg/m^3 ; no reference dose for oral exposure
- Office of Water, 2013: draft Health Advisory to serve as technical guidance in protecting public health when spills or contamination occur
 - for federal, state, and local officials
 - also for managers of public or community water systems
- IRIS, 2013: draft assessment of oral and inhalation hazards for public comment and peer review
 - OW's Health Advisory was superseded by the IRIS effort
- IRIS, 2016: Inhalation reference concentration raised to 0.5 mg/m^3 ; more analysis needed regarding oral exposure
- IRIS, 2018: Pending release of an IRIS Assessment Plan for oral exposure



Health Outcomes To Be Evaluated

- Gastric irritation
- Systemic toxicity (body weight)
- Metabolic acidosis* (and potentially musculo-skeletal toxicity)
- Hyperammonemia* (and potentially neurotoxicity)
- Developmental toxicity

**focus will be dose–response assessment, not hazard identification*

(A cancer assessment is not part of the scope, as the positive cancer studies are not conducive to derivation of a slope factor or reference dose)



Key Science Issues

- Susceptible populations and lifestages
 - individuals with impaired liver or kidney function (*the liver converts ammonia to urea, which is excreted by the kidneys*)
 - infants and children (*ammonia can cross the blood–brain barrier*)
 - individuals at risk for osteoporosis (*metabolic acidosis can cause bone loss*)
 - individuals infected with *Helicobacter pylori* (*this bacterium produces ammonia and causes stomach irritation and most non-cardia stomach cancers*)
- Attribution of responses to the ammonium cation or to the anion
- Palatability of ammonia to experimental animals
- Endogenous production of ammonia

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